UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,228	11/16/2005	Graham McIntyre	15373.0002	6730

27890 7590 04/30/2008
STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,228	MCINTYRE ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,8-10,12-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,8-10,12-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 December 2007 has been entered.

2. Claims 1 and 2 have been cancelled. Claims 3, 8, 9, 12, 15, 17, 18, and 19 have been amended.

3. Claims 3, 8-10, and 12-26 are pending and under consideration.

Rejections Moot/Withdrawn

4. The rejection of claims 1 and 2 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is moot in light of the cancelation of the claims.

5. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Matson et al (U.S. Pat. No. 4,599,310), is moot in light of the cancelation of the claims.

6. The rejection of claim 13 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn.

7. The rejection of claims 18-25 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.

Rejections Maintained

8. The rejection of claims 3, 8-10, 12, 14-17 and 26, under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is maintained for reasons of record.

Applicants argue that the amendment of claim 3 to require a pharmaceutically acceptable carrier no longer reads on a product of nature.

The examiner has considered applicants' argument, but does not find it persuasive.

Currently amended claim 3 recites "A pharmaceutical composition comprising 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides*, and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modiefies a cellular immune response."

The use of the term "composition comprising" allows for the presence of both living and dead whole cells, which would read on a product of nature which would contain both living and dead whole cells. Various *Rhodococcus* bacteria,for example, has been found in aquatic habitats, i.e., water (Bergey's Manual of Systemic Bacteriology, Vol. 2, pages 1472-1481). Water is a pharmaceutically acceptable carrier. Thus, the bacteria in water, i.e., a product of nature, fulfills the requirements of claims 3, 15, 16, and 17.

Claims 8-10 are directed to the composition according to claim 3 "for use as" a medicament or vaccine. The recitation of "for use as" is merely an intended use and as such places not patentable criterion on the composition claimed.

Claim 12 is directed to the composition of claim 3, further comprising "an antigen". Since no further restriction is placed upon the term "antigen", the source of the antigen can be the bacteria. Thus, the composition remains reading on a product of nature.

Claim 14 is directed to the composition of claim 3, further comprising two or more "antigens". Since no further restriction is placed upon the term "antigen", the source of the antigen can be the bacteria. Thus, the composition remains reading on a product of nature.

9. The rejection of claims 3 and 8-10 under 35 U.S.C. 102(b) as being anticipated by Matson et al (U.S. Pat. No. 4,599,310), is

Applicants' argue that Matson et al do not describe a pharmaceutical composition that includes 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides*, and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modiefies a cellular immune response nor administration of bacterial cells to patients.

The examiner has considered applicants' argument, but does not find it persuasive for reasons of record.

Currently amended claim 3 recites "A pharmaceutical composition comprising 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides*, and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modiefies a cellular immune response." Claims 8-10 are directed to the composition according to claim 3 "for use as" a medicament or vaccine. The recitation of "for use as" is merely an intended use and as such places not patentable criterion on the composition claimed.

Matson et al do teach a composition comprising a bacterium selected from the genera *Rhodococcus* in a medium containing an assimilable carbon source such as glucose, thus, reading on the bacteria in injectable glucose water. In the absence of evidence to the contrary, the compositions contain live and dead (10^4 to 10^{10}) whole bacteria.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Previously presented claims 18 and 19 are drawn to a method for immunizing a subject comprising administering a pharmaceutical composition and/or immune modulator composition according to any one of claim 1-3, wherein claim 2 defined the immune modulator composition as comprising an antigen and an adjuvant, wherein "said adjuvant" comprised a whole cell of a bacterium from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides*.

However, in newly amended claims 18 and 19, the immune modulator composition appears to be defined differently, i.e., no longer comprising an adjuvant, but remaining to be described as comprising a whole cell of a bacterium from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides*. It is therefore unclear what new definition of "immune modulator composition" is to be applied.

12. Newly amended claims 8-10, 12-17, and 26 are rejected under 35 U.S.C. 112, second paragraph, for insufficient antecedent basis.

The claims recite the limitation "An immune modulator composition or a pharmaceutical composition according to claim 3". There is insufficient antecedent basis for this limitation in the claims because claim 3 is only drawn to a pharmaceutical composition.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 25, 2008